

Remarks

Claims 1, 5-7 and 21-25 were pending.

Applicants have amended claim 1 to recite a method of detecting a colon or lung cancer marker, the method comprising detecting an expression profile of at least one nucleic acid in a cancer tissue from a human subject, wherein said at least one nucleic acid comprises a sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:12, and SEQ ID NO:26; comparing said expression profile to a normal tissue reference expression profile of said at least one nucleic acid; and determining whether the nucleic acid is overexpressed compared to the normal tissue reference expression profile, thereby to detect a marker of the colon or lung cancer. Support for the amendments to claim 1 is found in the original application at least, for example, at pages 9-11, 14-15, 18-19, 23, and 30-32, and in original claims 1 and 3.

Applicants have amended claims 5-7 to remove unnecessary words; to alter claim dependencies; and for consistency with the claims from which they depend. Applicants have canceled claims 21-25 without prejudice to Applicants' right to pursue their subject matter in the present application and in other applications.

Applicants have added new claims 26-30. Support for new claim 26 is found in the original application at least in original claim 7. Support for new claims 27-30 is found in the original application at least in Table 1.

Applicants have amended the specification to insert trademark designations.

Applicants submit no new matter is added by the present amendment.

Upon entry of the present amendment, claims 1, 5-7, and 26-30 will be pending and presented for consideration.

Objection to the Specification

The Office action objected to the specification as containing improperly demarcated trademarks. Applicants have amended the specification to insert trademark designations and request withdrawal of the objection.

Objection to the Claims

The Office action objected to claims 23-25. Without acquiescing to the objection, Applicants have cancelled claims 23-25, retaining the right to pursue their subject matter in this and other applications. Applicants request withdrawal of the objection in view of the cancellation of the claims.

Claim Rejections – 35 USC § 112, second paragraph

The Office action rejected claims 1, 5-7 and 21-25 as allegedly indefinite because of references to “NEK2, PLK1, ATR and CHEK1,” as the sole means to identify genes. Applicants have removed gene names from the claim and instead inserted nucleic acid sequence references. Applicants therefore request withdrawal of the rejection.

The Office action also rejected claims 1, 5-7 and 21-25 as allegedly indefinite for an alleged lack of a process step clearly relating back to the purpose or objective of the invention. Applicants submit that the amended claims clearly relate to the purpose or objective of the invention and request withdrawal of the rejection.

The Office action also rejected claim 5 as allegedly indefinite for reciting “the biological sample.” As amended, claim 5 no longer recites “the biological sample.” Applicants therefore request withdrawal of the rejection.

Claim Rejections – 35 USC § 112, first paragraph, written description, new matter

The Office action rejected claims 1, 5-7, and 21-25 as allegedly containing new matter for reciting “PLK1.” As amended, the claims no longer recite “PLK1.” Applicants request withdrawal of the rejection.

Claim Rejections – 35 USC § 112, first paragraph, written description

The Office action rejected claims 1, 5-7, and 21-25 as allegedly violating the written description requirement. The Office action pointed specifically to the breadth of the genus of “cancer markers” and of “NEK2, ATR and CHEK1.” The Office action appears to acknowledge that the application teaches SEQ ID NO:26, SEQ ID NO:1, and SEQ ID NO:12 and their

usefulness as markers for colon cancer, but argues that the disclosure of these species of the invention is insufficient to demonstrate possession of the claimed genus.

Applicants disagree. While the application does teach that “slight” sequence alterations can be encompassed by the present invention, this does not support and is indeed inconsistent with the examiner’s assertion that “NEK2, ATR and CHEK1” nucleic acids encompass genes that are “structurally … unrelated to SEQ ID NO:26, SEQ ID NO:1, and SEQ ID NO:12” (Office action, page 10).

Nevertheless, to promote prosecution, Applicants have replaced the gene names in the claims with sequence identifiers solely to remove any ambiguity regarding which human genes’ nucleic acids are detected in the presently claimed invention.

Applicants submit that the written specification demonstrates that Applicants were in possession of the presently claimed invention, including the genus of claimed cancer markers, at the time of filing of the application.

Applicants have also amended the claims to recite detecting a colon or lung cancer marker. The Office action acknowledged that the nucleic acid sequences of SEQ ID NO:26, SEQ ID NO:1, and SEQ ID NO:12 are overexpressed in human colon adenocarcinoma cells. Table 6a shows that each of the claimed nucleic acid sequences are overexpressed in colon and lung cancer (and, in several instances, in other cancers as well).

The nucleic acids and their uses described in the application demonstrate possession of the claimed invention. Applicants therefore request reconsideration and withdrawal of the rejection.

The Office action also rejected claims 23-25, alleging that the specification does not correlate any particular expression profile with prognosis. To promote prosecution, Applicants have canceled claims 23-25 without acquiescing to the rejection. Applicants request withdrawal of the rejection in view of the cancellation of the claims.

Claim Rejections – 35 USC § 112, first paragraph, written description

The Office action rejected claims 1, 5-7, and 21-25, “because the specification, **while being enabling for using** a method of detecting colon adenocarcinoma markers comprising detecting an expression profile of at least one nucleic acid in a colon cancer tissue from a human subject, wherein said at least one nucleic acid is selected from the group of SEQ ID NO:26, SEQ ID NO:1, and SEQ ID NO:12, wherein said at least one nucleic acid is overexpressed compared to a normal colon tissue reference control,” (Office action, page 11) allegedly does not reasonably enable use of the invention commensurate in scope with the previously pending claims.

The Office action alleged that the nucleic acids of SEQ ID NO:26, SEQ ID NO:1, and SEQ ID NO:12 would not be considered markers of all types of cancer. Applicants have amended the claims to recite “colon or lung” cancer. The application demonstrates the overexpression of each of SEQ ID NO:1, SEQ ID NO:12, and SEQ ID NO:26 in colon and lung cancer—see Table 6A. Thus, the application enables use of the invention with a scope reasonably commensurate with the scope of the pending claims.

The Office action alleged that the artisan cannot predict whether the proteins encoded by the nucleic acids are also overexpressed in cancer. Applicants disagree, noting that none of the examples cited by the examiner show a nucleic acid which, when overexpressed in a tissue, failed to induce additional protein expression. Nevertheless, to promote prosecution, Applicants have amended the claims to recite expression profiles of nucleic acids.

The Office action alleged that the previously pending claims encompassed non-human genes. Applicants disagree, but have amended the claims to recite sequence identifiers to remove any question whether the invention relates to the detection of a human nucleic acid in a human.

The Office action also discussed claims 23-25, which Applicants have canceled without prejudice.

In view of the claim amendments, the teachings of the specification relating to the expression profiles of SEQ ID NO:1, SEQ ID NO:12, and SEQ ID NO:26 in colon and lung

cancer, and the level of skill in the art at the time the application was filed, Applicants submit that the application enables the claimed invention. Applicants therefore request reconsideration and withdrawal of the rejection.

Claim Rejections – 35 USC § 102—Bischoff and Mack

Claims 1, 5-7 and 21-22 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bischoff *et al.* EMBO J. 17(11):3052-3065 (“Bischoff”). Claims 1, 5-7 and 21-22 are also rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Application Publication No. US2004/0063108 (“Mack”).

Neither Bischoff nor Mack appears to identify SEQ ID NO:1, SEQ ID NO:12, or SEQ ID NO:26 as markers for colon or lung cancer. Accordingly, neither Bischoff nor Mack anticipates the claimed invention.

Applicants request withdrawal of both rejections.

Claim Rejections – 35 USC § 102—Venter

Claims 1, 5-7 and 21 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by WO 2002/068579 (Venter).

Venter does not specifically identify SEQ ID NO:1, SEQ ID NO:12, or SEQ ID NO:26 as specifically useful as markers for colon or lung cancer. Venter does not provide a specific, enabling disclosure of the presently claimed invention.

Applicants request withdrawal of the rejection.

Claim Rejections – 35 USC § 102—Wai

Claims 1, 21 and 22 are rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Wai *et al.* (2002) Int. J. Oncol. 20(3):441-51 (“Wai”).

Wai does not teach SEQ ID NO:1, SEQ ID NO:12, or SEQ ID NO:26 as markers for colon or lung cancer. Wai therefore does not anticipate the presently claimed invention.

Applicants request withdrawal of the rejection.

Claim Rejections – double patenting

Claims 1, 5-7 and 21-22 are provisionally rejected as allegedly unpatentable over claims 7-8 of copending application 10/751,736 under the judicially-created doctrine of obviousness-type double patenting.

The claims of 10/751,736 relate to GPR49, which Applicants believe to be distinct from the presently claimed cancer markers. Applicants therefore request withdrawal of this provisional rejection.

Examiner Duffy is invited to telephone the undersigned attorney to discuss any remaining issues.

Respectfully submitted,



Brian Fairchild, Ph.D.
Attorney for Applicants
Kirkpatrick & Lockhart Preston Gates
Ellis LLP
State Street Financial Center
One Lincoln Street
Boston, Massachusetts 02111-2950

Date: May 21, 2007

Reg. No. 48,645

Tel. No.: (617) 261-3169

Fax No.: (617) 261-3175